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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,823	06/25/2003	Olivier De Lacharriere	016800-515	1993

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EXAMINER	
DUTT, ADITI	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/602,823	LACHARRIERE ET AL.	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-54 and 64-67* is/are pending in the application.

4a) Of the above claim(s) *39,40,45,46 and 64-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37,38,41-44 and 47-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 May 2008 has been entered.

Status of Claims

2. The amendment filed on 14 April 2008 has been entered into the record and has been fully considered.

3. Claims 1-36 and 55-63 have been cancelled.

4. Claims 37-38, 41-44, 47-54 drawn to a non-therapeutic method of evaluating level of skin sensitivity and identifying persons having sensitive skin are being considered for examination in the instant application.

Response to Amendment

Withdrawn objections and/or rejections

5. Upon consideration of the Applicant's amendment, all claim objections and rejections, not reiterated herein have been withdrawn, as overcome by cancellation and/or amendment of claims (14 April 2008).

6. Rejection of claims under 35 USC § 112, first paragraph, written description is withdrawn after consideration of claim amendments and Applicant's persuasive argument.

7. Rejection of claims 55-63 under 35 USC § 103(a) as being obvious over Robinson et al, in view of Hahn et al, is withdrawn due to the cancellation of the claims.

Claim objections

8. Claims 43 and 44 are objected to because of the following informalities: Claims 43 and 44 refer to step "a)" of claim 37. However, there is no step "a)" in claim 37. Appropriate correction is required.

Rejections maintained

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 37-38, 41-42, 47-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (2001, cited by Applicant).

12. The claims recite a non-therapeutic method of identifying persons having sensitive skin by application of an aqueous or non-aqueous alcoholic solution comprising a stimulant, a capsaicinoid or capsaicin (between 1×10^{-6} % and 5×10^{-4} %) comprising a physiologically acceptable aqueous alcohol vehicle to a skin area, and deducing information regarding the skin reactivity as a function of the unattractive sensations (claims 37-38, 41-42 and 47-54).

13. Robinson et al. teaches a method of assessing skin irritation by using 100-10,000 μM capsaicin in 80% ethanol on filter papers onto the left and right forearm of subjects, waiting for 3 minutes and recording the sensory responses for both treatment and control skin areas, such as stinging, burning or itching

(see figure 6, page 210; pages 206, 207, 211). Robinson et al. further teaches that the concentration of capsaicin was increased by a factor between 1 and 10 (see figure 5, page 210) until a moderate sensory response such as burning or itching was elicited.

14. Robinson et al. does not teach the concentration of capsaicin to fall in the range of 1×10^{-6}% and 5×10^{-4}% or 1×10^{-6}% and 1×10^{-4}% by weight. Robinson et al. also does not teach a concentration of ethanol between1% to 50%. It is noted that capsaicin of Robinson et al. is a member of the claimed capsaicinoid. However, since each individual responds to a compound differently, the determination of concentration curves for the effectiveness of a compound is routinely practiced in biological sciences. Therefore, optimization within prior art conditions or through routine experimentation is obvious to one skilled in the art. As stated in MPEP 2144.05:

> "The differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages". *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382; Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 UDPQ2d 1843 (Fed. Cir.).*

15. It would have been, therefore, obvious to the person of ordinary skill in the art at the time the claimed invention was made to determine the optimal ranges of capsaicin and alcohol content in the solution of the skin sensitivity testing

method as taught by Robinson et al. The person of ordinary skill in the art would have been motivated to perform such tests on sensitive skin to assess the response to various products and chemicals. The person of ordinary skill in the art would have expected success because the method of testing sensory response to capsaicin was well established in the art at the time the invention was made.

16. Thus, the claimed invention as a whole was *prima facie* obvious over the teachings of the prior art.

Response to Argument

17. Applicant traverses the rejection on the basis of an alleged different purpose demonstrated by Robinson et al. Specifically Applicant asserts that Robinson et al's method is directed towards "irritant potential of topical ingredients or products" and "that subjects were tested regardless the sensitivity of their skin". Applicant further argues that while the instant application relates to a method identifying a person with sensitive skin, Robinson et al aim at characterizing a product. Applicant points out to Robinson's purpose of the study as geared to a method that would have the advantage of being less invasive than other bioassay procedures for identifying inflammatory markers. Applicant argues that Robinson et al do not reduce the stimulant dose to identify a person with sensitive skin, as noted in the instant application wherein sensitivity is characterized by using very low concentration of the nervous system stimulant.

Applicant alleges that because Robinson et al. do not describe sensitive skin, nor correlates skin sensitivity with peripheral nervous stimulants, it would "not have been obvious to a skilled artisan to try to vary a peripheral nervous stimulant dose" or "reduce the stimulant dose" for identifying skin sensitivity. Applicant thus requests the rejection to be withdrawn.

18. Applicant's arguments have been fully considered but have not been found to be persuasive. The claimed invention is directed to a method of evaluating the level of skin sensitivity. Robinson et al. defines sensory skin irritation as comprising "bothersome symptoms", equivalent to the instantly claimed "unattractive sensation", comprising stinging, burning, itching etc., in other words, sensory skin irritation induced by skin irritants or products that result in unattractive sensation. Regardless of whether Robinson et al.'s purpose is to characterize a product, the reference still teaches a method to assess the neurosensory skin irritation using capsaicin, comprising the same steps as in the claimed invention. Also, Robinson et al's method of classification of subjects having sensitive skin vs. normal skin, comprising increasing the concentration of capsaicin until a moderate sensory response such as burning or itching is elicited, is in coherence with the classic protocol of increasing or decreasing the concentrations of a stimulant until the limits of threshold for detecting the stimulus is estimated (Green et al. J Toxicol – Cut Ocular Toxicol 14: 23-48, 1995; page 36, para 4; page 37. para 1). Furthermore, contrary to Applicant's allegation about the dose of the stimulant, as stated above, optimization within prior art

conditions or through routine experimentation is obvious to one skilled in the art. It would have been, therefore, obvious to the person of ordinary skill in the art at the time the claimed invention was made to determine the optimal ranges of capsaicin and alcohol content in the solution of the skin sensitivity testing method as taught by Robinson. The person of ordinary skill in the art would have been motivated to perform such tests on sensitive skin to assess the response to various products and chemicals (Robinson). Therefore, the claimed invention as a whole is prima facie obvious over the teachings of Robinson et al. and stay rejected..

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20. Claims 43 and 44 recite "between 1 and 3 applications of the solution" or "3 applications". The limitation is vague and unclear because it is not discernible as to whether the applications should be between 1 and 3 times in quick

succession, requires a time lag between each application, or should be applied simultaneously at three different skin locations.

Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

21. Claims 37-38, 41-44, and 47-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a non-therapeutic method of identifying persons having **sensitive skin to a capsaicinoid**, comprising applying a capsaicinoid to a skin area such as bend of the arm, face, ear lobe etc. of an adult individual (> 18 years old, specifically between 18-65), does not reasonably provide enablement for a method of identifying persons having sensitive skin to any stimulant by applying to any skin area of an individual of any age, in particular infants, children or elderly (>65 years) individuals. The preamble of the claim is interpreted as a non-therapeutic method of identifying persons having sensitive skin in general, i.e. having sensitivity to any product, environment, chemicals, etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

22. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, include the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

23. Claims 37-38, 41-44, 47-54 are directed to a non-therapeutic method of identifying persons having sensitive skin by 1-3 applications comprising a (1) a peripheral nervous system stimulant, capsaicin (between 1×10^{-6} % and 5×10^{-4} %) comprising a physiologically acceptable aqueous alcohol vehicle to a skin area and recording the unattractive sensation (claims 37-38, 41-44, 47-54).

24. The specification teaches a non-therapeutic method of evaluating skin sensitivity using peripheral nervous system stimulant (capsaicin) between 1×10^{-6} % and 5×10^{-4} % by weight relative to the weight of the composition, by gradually increasing the concentration of capsaicin by a factor of 1-10, and record the resulting unattractive sensation perceived (page 8, para 0035; page 13, para 0060; page 14, 15, paragraphs 0064 and 0066). The specification defines sensitive skin as that which is "hyper-reactive to various factors acting by non-immunological mechanisms", wherein the stimuli can be in various physical or chemical forms (page 2, para 0007). The specification further teaches that skin discomfort, like itching, stinging etc. are manifested mostly on the facial skin

(page 3, para 0011). The specification also teaches that symptoms producing the unattractive sensation or skin discomfort could be triggered by various external and internal factors such as environmental, emotional, physiological, dietary and topical applications (page 3, para 0012; page 4, para 0016). Additional variants have been established by epidemiological studies indicating that women are more sensitive (page 2, para 0009), and that aging diminishes sensitivity (page 2, para 0009). The specification further exemplifies the skin sensitivity in 150 Parisian women, aged 18-60 years (Example 7-10). However, the specification does not disclose any methods or working examples for identifying persons having sensitive skin to any stimulant, wherein the stimulant can be applied to any skin area of an individual of any age, gender, ethnicity, etc. Undue experimentation would be required by one skilled in the art, to determine sensitive skin to any stimulant by determining the sensitivity to a single stimulant (capsaicin).

25. Relevant literature teaches that sensitivity is the minimum concentration required to produce a perceptible sensation (or irritation) (Green et al; page 25, para 3). Green et al further teach that responsiveness of individuals to different chemicals is different and that "an individual's response to one chemical could not always be predicted from his or her response to the other chemical" (page 25, para 4). Jourdain et al (Contact Dermatitis, 46: 162-169,) teach that individuals from different ethnicities exhibit different skin sensitivity due to differences in skin physiology (increased number of stratum corneum layers in

the skin, increased lipid content, etc.) (page 162, para 2), and that younger women (23-26 years) are more sensitive that older women (30-45 years) (Green et al., pages 33-34). Furthermore, different regions of the skin elicit varied sensitivity to stimulants, e.g. the facial skin is more sensitive than the arm to various topical creams and cosmetics (Green et al 26, para 1). Because of the unpredictability of different skin sensitivities, Green et al recommend that multiple stimulants should be used for identifying skin chemosensory function (page 43, para 1). Over and above the intrinsic differences, the partial subjective nature of skin sensitivity testing in the state-of-the-art protocols, contributes to significant intra and inter individual variations in sensitivity to the nature and concentration of stimulants. Therefore, Green et al. caution that "it is risky to draw conclusions about individual sensitivities based on the result of a single exposure" (page 43, para 3). Because of all the aforesaid variations in skin sensitivity determined by biochemical, physiological, age, gender, sex, ethnicity, and other external/internal factors, undue experimentation by a skilled artisan will be required to identify persons having sensitive skin to any stimulant, using capsaicin as the stimulant for testing. The specification or the relevant art does not teach the identification of skin sensitivity to all stimulants by probing with one stimulant only. It is suggested that independent claims 37 and 53 should read "....identifying persons having sensitive skin to capsaicinoid (or capsaicin))...." for clarifying enablement issues.

26. Due to the large quantity of experimentation necessary to identify persons with sensitive skin by applying capsaicin; lack of direction/guidance presented in the specification regarding the same; the complex nature of the invention due to the large amount of internal and external factors; the state of the prior and post art which has yet to identify skin sensitivity using one stimulant only and, the unpredictability of subjective measurements of unattractive sensations perceived; undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Conclusion

27. No claims are allowed.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov/. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD
20 August 2008

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649